DETAILED ACTION

Applicants preliminary amendment filed February 22, 2005 has been received and entered. Claims 1-9, 29, and 31-62 have been cancelled. Accordingly, claims 10-28, and 30 are pending in the instant application.

Claim Objections

1. Claims 10-28 and 30 are objected to because of the following informalities:

Reference to Genebank accession numbers. Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table or deposit "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Claim Rejections - 35 USC § 112

2. Claims 10-28 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "functional fragment, analog or derivative thereof." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what amount of chemical

modification can take place and still be encompassed by the terms functional fragment, analog or derivative? Likewise, at what point is the modification so severe as to be no longer encompassed by the terms functional fragment, analog or derivative? Without a clear definition as to the terms functional fragment, analog and derivative, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

3. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of “other chemical modification.” One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, is a covalent bond required to be broken or formed for a chemical modification, or would the presence of hydrogen bonding be sufficient to be considered a chemical modification? Without a clear definition as to the metes and bounds of the term "other chemical modification" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

4. Claims 10, 12 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of “substantially as denoted by SEQ ID NO: 32/substantially homologous to.” One of skill in the art would be unable to

determine the metes and bounds of the claimed invention. For instance, what level of homology is encompassed by “substantially as denoted by” (e.g., 80%, 50%, 25%, etc)?” Without a clear definition as to the metes and bounds of the term "substantially as denoted by" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10-17, 20-25, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Docette-Stamm et al.

The claims are directed to a method of inhibiting an invasive and/or non-invasive infection of Gram-positive pathogenic bacteria in a mammalian subject, comprising administering to said subject an inhibitory effective amount of an isolated and purified peptide or of a composition comprising the same, which peptide comprises an amino acid sequence substantially homologous to the amino acid sequence encoded by the SilCR ORF of the sil locus at position 2985 to 2863 of the complementary strand of the genomic sequence of Group A Streptococcus bacteria specified in GenBank accession number AF493605 or any functional fragment, analog or derivative thereof.

Docette-Stamm et al (US Patent Number 6,380,370) disclose of isolated polypeptides useful for antibacterial vaccines. (See paragraph 13). Docette-Stamm et al further disclose of one antibacterial peptide having 48% identity to SEQ ID NO: 32 of the instant invention. (See attached alignment; amino acids 253-268 of SEQ ID NO: 4376 of Docette-Stamm et al).

Given that Docette-Stamm et al disclose of methods for inhibiting pathogenic bacteria via the administration of isolated polypeptides which are substantially homologous or functional fragments, or analogs or derivatives of the amino acid sequence encoded by the SilCR ORF of the sil locus at position 2985 to 2863 of the complementary strand of the genomic sequence of Group A Streptococcus bacteria specified in GenBank accession number AF493605, the disclosure of Docette-Stamm et al is deemed to anticipate the instantly filed claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 10-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Docette-Stamm et al in view of Spatola et al.

The claims are directed to a method of inhibiting an invasive and/or non-invasive infection of Gram-positive pathogenic bacteria in a mammalian subject, comprising administering to said subject an inhibitory effective amount of an isolated and purified peptide or of a composition comprising the same, which peptide comprises an amino acid sequence substantially homologous to the amino acid sequence encoded by the SilCR ORF of the sil locus at position 2985 to 2863 of the complementary strand of the genomic sequence of Group A Streptococcus bacteria specified in GenBank accession number AF493605 or any functional fragment, analog or derivative thereof, wherein the peptide is conformationally constrained.

The teachings of Docette-Stamm et al are set forth above.

Docette-Stamm et al do not teach of conformationally constrained peptides.

Spatola et al (US Patent Number 6,008,058) teach that cyclic peptides have significant advantages including stabilizing the peptides against many forms of proteolytic degradation. (See Summary).

Given that Docette-Stamm et al have taught of inhibiting pathogenic bacteria via

the administration of isolated polypeptides which are substantially homologous to the amino acid sequence encoded by the SilCR ORF of the sil locus at position 2985 to 2863 of the complementary strand of the genomic sequence of Group A Streptococcus bacteria specified in GenBank accession number AF493605 and that 2) Spatola et al have taught of the advantages of cyclic peptides over linear peptides including decreased proteolytic degradation, it would have been prima facie obvious to have generated cyclic peptides as taught by Spatola et al on the peptides for inhibiting bacterial growth as taught by Docette-Stamm et al.

It is noted that the references do not teach administration of the peptide in an amount between 0.5µg/kg to 100mg/kg of body weight, however determining the precise amount of protein which is optimal for inhibiting bacterial growth is merely the result of optimizing a result effective variable. As set forth in In re Boesch, 617, F.2d 272, 276, 205 USPQ 215, 219, (CCPA 1980), it is normally within the skill in the art to optimize a result effective variable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shannon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
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